

**REMARKS**

Claims 1-31 and 38-95 are currently pending. Claims 1-2, 20-21, 53 and 71-72 have been amended. Support for the amendments to the claims is seen on page 2, lines 28-30 and page 4, lines 20-30. Applicants maintain that no new matter has been added thereby and therefore request that these amendments be entered.

Rejection under 35 USC 102(b):

(a) Claims 1-31, 50, 53-80 and 93 are rejected under 35 USC 102(b) as being anticipated by Freund *et al* (DE 19653969) (US 2001/0008632 is being used as the translation for the German document).

Applicants respectfully traverse. Freund *et al.* relates generally to aqueous medicament preparations. Although Freund *et al.* may mention many possible components for fabricating inhalation aerosols, Freund *et al.* does not provide any disclosure or guidance toward the specifically claimed invention. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co.*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987); *see also* M.P.E.P. § 2131. The ordinarily skilled artisan is not directed to the claimed invention with the limitations that are instantly claimed. Accordingly, there is no anticipation of the claimed invention by Freund *et al.* and applicants respectfully request that the Examiner reconsider and withdraw this rejection.

(b) The Examiner also rejected claims 1-31, 50, 53-80 and 93 under 35 U.S.C. § 102(b), as allegedly anticipated by Bozung *et al.* (DE 19921693; U.S. Patent No. 6,433,027 being used as a translation thereof).

Although Bozung *et al.* is directed at pharmaceutical compositions comprising combinations of Beta sympathomimetics and anticholinergics. Bozung *et al.* does not provide any disclosure or guidance toward the specifically claimed invention. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co.*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987); *see also* M.P.E.P. § 2131. The ordinarily skilled artisan is not directed to the claimed invention with the limitations that are instantly claimed. Accordingly,

the rejection under Section 102(e) should be reconsidered and withdrawn.

Rejections under 35 USC 103(a):

(a) The Examiner also rejected claims 38 to 49, 51, 52, 81 to 92, 93, and 95 under 35 U.S.C. § 103(a), as allegedly unpatentable over Freund *et al.* as applied to claims 1+31, 50, 53-80 and 93 above, and further in view of Weston *et al.* (WO 91/14468).

In response, applicants respectfully traverse the Examiner's rejection under 35 U.S.C. § 103(a) and maintain that the Examiner has failed to establish a *prima facie* case of obviousness against the instant invention. A *prima facie* case of obviousness requires the satisfaction of three criteria: (i) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings; (ii) there must be a reasonable expectation of success; and (iii) the references when combined must teach or suggest all of the claim limitations. M.P.E.P. § 2143.

Neither Freund *et al.* nor Weston *et al.*, alone or in combination, renders the special formulation of applicants claimed invention obvious, however, since neither reference, alone or in combination discloses, suggests, or even hints to one of skill in the art, much less with the required reasonable expectation of success, of the claimed composition of applicants' invention. As pointed out above, with respect to the anticipation rejection, Freund *et al.* does not provide any disclosure or embodiment of the claimed invention.

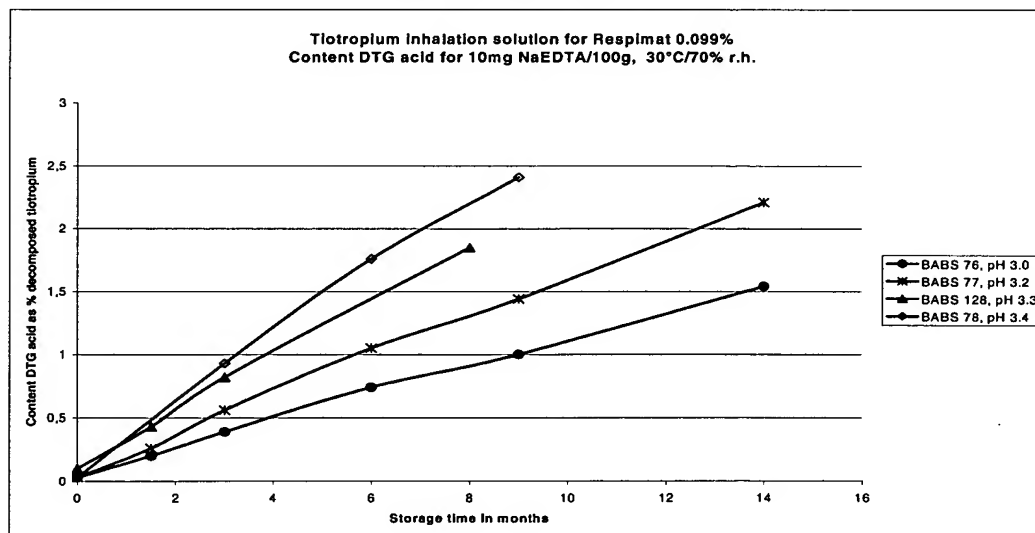
Since the Examiner is relying solely on Freund *et al.* to teach the formulation to be used in the nebulizer of Weston *et al.*, applicant maintains that Freund *et al.* is deficient in teaching the formulation used in applicants' claimed invention. The Examiner has the burden of showing a *prima facie* case of obviousness. *In re Bell*, 26 U.S.P.Q.2d 1529, 1530 (Fed. Cir. 1993); *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992). The fact that Freund *et al.* nor Weston *et al.* contain elements of applicants' claimed invention alone does not render the claimed invention obvious. Rejecting claims solely by finding prior art corollaries for the claimed elements would permit an Examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention, which is an illogical and inappropriate process by which to determine patentability.

*Sensonics, Inc. v. Aerosonic Corp.*, 38 U.S.P.Q.2d 1551, 1554 (Fed. Cir. 1996); *In re Rouffet*, 47 U.S.P.Q.2d 1453 (Fed. Cir. 1998). Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion or incentive to do so. *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984). Virtually all inventions are combinations of old elements. *Environmental Designs, Ltd. v. Union Oil Co.*, 218 U.S.P.Q. 865, 870 (Fed. Cir. 1983). Thus, the mere mention of elements of applicants' claimed invention in these references does not alone render obvious their particular combination. As applicants maintain that the Examiner has failed to establish a *prima facie* case of obviousness against the instant invention, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Assuming arguendo that the Examiner established a *prima facie* case of obviousness, the claimed parameters provide the preparation with unexpected activity. The discussion below exemplifies the unexpected activity of the formulation. When an aqueous formulations containing 0.099% tiotropium, 10mg/100ml sodium edentate and 10mg/100ml benzalkonium chloride were adjusted with HCl to pH values of 3.0, 3.2, 3.3 and 3.4 respectively and stored at 30°C/70% r.h. The decomposition of tiotropium was measured by determining content of decomposition product dithienyl-glycolic acid (DTG acid).

The results for the 4 different formulations are summarized in the diagram below.

**Decomposition of tiotropium bromide at different pH values:**



Surprisingly, it has been found that stability of tiotropium bromide is in the range of 3.0 to 3.4 strongly pH dependent. Whereas at the pH of 3.0, the tiotropium solutions are relatively stable. Quicker degradation is seen at pH levels of 3.2, thereby leading to a larger amount of DTG acid.

The strong pH dependency of the stability of tiotropium bromide containing aqueous solutions is neither taught nor rendered obvious by the references alone or in combination.

Applicants maintain that the above remarks and amendments overcome the Examiner's rejection or render the Examiner's rejections moot and thus withdrawal of the rejection is respectfully requested.

Obviousness-type Double Patenting:

(a) Claims 1-31 and 38-95 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-81 of US 6,890,517 B2. In view of the arguments outlined in the paragraphs above with reference to the unexpected activity of the preparation at the pH levels claimed, Applicants believe that the rejection is rendered moot and withdrawal of the same is respectfully requested.

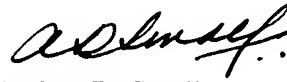
(b) Claims 1-31, 50, 53-80 and 93 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of US 6,908,928 in view of Freund et al (US 2001/0008632). In view of the arguments outlined in the paragraphs above with reference to the unexpected activity of the preparation at the pH levels claimed, Applicants believe that the rejection is rendered moot and withdrawal of the same is respectfully requested.

In view of the above amendments and remarks, Applicants respectfully submit that this application is now in condition for allowance and earnestly request such action.

If any points remain at issue which can best be resolved by way of a telephonic or personal interview, the Examiner is kindly requested to contact the undersigned attorney at the telephone number listed below.

AMENDMENT  
U.S. Appln. No. 10/735,959

Respectfully submitted,

A handwritten signature in black ink, appearing to read "A. D. Small".

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